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Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Disclaimer

Change Summary

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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LCD	Transurethral Waterjet Ablation of the Prostate	<u>L38682</u>	J5 - Wisconsin Physicians Service	IA, KS, MO, NE
LCA	Billing and Coding: Transurethral Waterjet Ablation of the Prostate	<u>A58209</u>	Insurance Corporation (Part A/B MAC)	
LCD	Water Vapor Thermal Therapy	L37808	J6 - National Government Services, Inc.	
LCA	for LUTS/BPH Billing and Coding: Water Vapor Thermal Therapy for LUTS/BPH	A56590	JK - National Government Services, Inc. (Part A/B MAC)	CT, NY, ME, MA, NH, RI, VT
LCD	Fluid Jet System Treatment for LUTS/BPH	L38367	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
LCA	Billing and Coding: Fluid Jet System Treatment for LUTs/BPH	<u>A56797</u>	JK - National Government Services, Inc. (Part A/B MAC)	CT, NY, ME, MA, NH, RI, VT
LCD	Laser Ablation of the Prostate Billing and Coding: Laser Ablation of the Prostate	<u>L34090</u> <u>A56467</u>	J15 - CGS Administrators, LLC (Part A/B	кү, он
LCA LCD	Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia	L38378	J15 - CGS	
LCA	Billing and Coding: Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia (BPH)	<u>A57926</u>	Administrators, LLC (Part A/B MAC)	кү, он
LCA	Billing and Coding: Rezum System for Benign Prostatic	<u>A56083</u>	J15 - CGS Administrators, LLC (Part A/B MAC)	кү, он
LCD	Transurethral Waterjet Ablation of the Prostate	<u>L38705</u>	JE - Noridian	CA, HI, NV, American Samoa,
LCA	Billing and Coding: Transurethral Waterjet Ablation of the Prostate	A58227	Healthcare Solutions, LLC	Guam, Northern Mariana Islands

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LCD	Transurethral Waterjet Ablation of the Prostate	<u>L38707</u>	JF - Noridian	AK, AZ, ID, MT, ND, OR, SD,
LCA	Billing and Coding: Transurethral Waterjet Ablation of the Prostate	<u>A58229</u>	Healthcare Solutions, LLC	UT, WA, WY
LCD	Transurethral Waterjet Ablation of the Prostate	<u>L38712</u>	JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCA	Billing and Coding: Transurethral Waterjet Ablation of the Prostate	<u>A58243</u>	JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, D.C., MD, NJ, PA
LCD	Transurethral Waterjet Ablation of the Prostate	<u>L38549</u>	JJ - Palmetto GBA (Part A/B MAC)	AL, GA, TN
LCA	Billing and Coding: Transurethral Waterjet Ablation of the Prostate	<u>A58008</u>	JM - Palmetto GBA (Part A/B MAC)	NC, SC, VA, WV
LCD	Transurethral Waterjet Ablation of the Prostate	L38726	JN - First Coast Service	
LCA	Billing and Coding: Transurethral Waterjet Ablation of the Prostate	<u>A58264</u>	Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

Benign prostatic hyperplasia (BPH) is caused by the growth of benign (noncancerous) prostate cells which enlarge the prostate gland. The gland may push against the bladder and urethra, causing lower urinary tract symptoms (LUTS) that include increased frequency of urination, hesitancy, nocturia (urinating at night), urgency and weak urine stream. These symptoms typically appear slowly and progress gradually over time. The likelihood of being affected by BPH increases with age and is common in males over 50 years of age.

Treatment focuses on reducing bothersome symptoms. Early nonsurgical management options include, but may not be limited to, the following:

• Alter lifestyle modifiable factors such as alcohol, caffeine and fluid intake and contributing medications when possible;

AND/OR

• Prescription medication when medically appropriate and not contraindicated

If symptoms worsen, other treatment options include, but may not be limited to, the following:

Surgical Therapies:

Prostatectomy (open, laparoscopic) is performed when the prostate is greatly enlarged, when there are other complicating factors or if the bladder has been damaged and needs repair. In this procedure, an incision (or multiple small incisions) is made in the lower abdomen or perineum and the enlarged tissue is removed from the gland.

Transurethral electrical vaporization of the prostate (TUEVP, TUVP, TVP) or transurethral vapor resection (TUVRP), is performed using a grooved roller-ball electrode with a large surface area that uses a cutting current. During the procedure, the ball is rolled over the prostate tissue multiple times to vaporize the tissue to the desired depth.

Transurethral incision of the prostate (TUIP) does not remove prostate tissue. The urethra is widened by making several small cuts into the prostate and the neck of the bladder where the urethra and the bladder join. This reduces the pressure on the urethra and makes urination easier. TUIP is utilized when the prostate is not greatly enlarged.

Transurethral microwave thermotherapy (TUMT) heats the prostate using a microwave antennae mounted on a urethral catheter. The catheter is inserted into the urethra where low-energy or high-energy microwave heat destroys excess prostate tissue.

Transurethral needle ablation (TUNA) or radiofrequency needle ablation (RFNA) uses low-level radiofrequency energy to treat the prostate. Using a cystoscope-like device, inserted through the urethra, twin needles are placed on either side of the prostate. Each needle emits radiofrequency energy that burns away a defined region of the prostate while shielding the urethra from heat.

Transurethral resection of the prostate (TURP) is considered the gold standard for BPH treatment. A resectoscope is inserted through the urethra to deliver fluids to the prostate during the procedure. The resectoscope uses an electrical loop to cut and vaporize tissue and seal blood vessels. The excised tissue is carried to the bladder and flushed out of the body by irrigation fluids.

Water Vapor Thermal Therapy (WVTT) (Rezum System) delivers sterile water vapor (steam) transurethrally directly into hyperplastic tissue. Heat is released as the vapor condenses, causing cell death.

Laser Therapy

Laser therapy is minimally invasive and uses laser generated heat to vaporize or coagulate obstructing prostate tissue. The device is passed through the urethra to the prostate using a cystoscope to deliver bursts of energy which destroy and shrink the prostate tissue. Laser surgery typically results in less blood loss. Types of laser therapy include, but may not be limited to:

- Contact laser ablation of the prostate (CLAP)
- Holmium laser ablation/enucleation/resection (HoLAP, HoLEP, HoLRP)
- Interstitial laser coagulation (ILC)

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- Noncontact visual ablation (VLAP)
- Photoselective vaporization of the prostate (PVP)
- Thulium laser enucleation of the prostate (ThuLEP)

Transperineal laser ablation (TPLA) involves percutaneous insertion of laser fibers, through the perineal skin and into the prostate. The delivery of laser generated heat is used to purportedly vaporize obstructing prostate tissue. The insertion of the fibers and monitoring are carried out under ultrasound guidance. The system has a dedicated transrectal ultrasound probe.

Stents

Permanent urethral stents are placed into the urethra and expanded to relieve the obstruction.

Temporary (removable or biodegradable) prostatic urethral stents (iTind) perform in a similar manner and function but do not remain in the body permanently.

Additional Therapies

Absolute ethanol injection into the prostate is a technique theorized to cause coagulation necrosis (chemoablation), which destroys the tissue.

Cryosurgical ablation, also known as cryotherapy or cryosurgery, proposes the use of extreme cold temperatures by liquid nitrogen or argon gas to destroy tissue. When used internally, the liquid nitrogen or argon gas is circulated through a cryoprobe which freezes the surrounding cells. After the destroyed cells thaw, they are absorbed by the body.

High-intensity focused ultrasound (HIFU) is the use of imaging ultrasound to deliver targeted high-intensity ultrasound that rapidly elevates the temperature in a precise focal zone. The increased tissue temperature is suggested to kill excess prostate tissue. Ablatherm, Sonablate and TULSA-PRO system are examples of US Food & Drug Administration (FDA) approved high-intensity ultrasound systems.

Plasma kinetic vaporization (PKVP) or button procedure proposes the use of two mutually isolated electrodes (active and return) to form a complete circuit with the tissue lying between them. The electrical conduction path is formed by a saline irrigant. Radiofrequency energy is used to convert the conductive medium into a plasma field, which vaporizes tissue upon contact. A resectoscope, an instrument that contains the electrodes and is equipped with a wide-angle telescope, is passed retrograde through the urethra to the prostate.

Prostate artery embolization aims to reduce the blood supply to the prostate gland causing tissue death and subsequent shrinkage. The procedure is performed using a percutaneous transfemoral approach with microcatheters introducing embolization agents such as polyvinyl alcohol (PVA), gelatin sponge and other synthetic biocompatible materials which expand once delivered within the artery, blocking blood flow. Embosphere Microspheres and SwiftNINJA are examples of FDA-approved methods.

Prostatic Urethral Lift (PUL) is an implantable transprostatic tissue retractor system consisting of a delivery device inserted through the urethra, which then deploys an implant through the prostate. Implant increases

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urethral patency by providing prostate lobe tissue retraction while preserving the potential for future procedures. An example of an FDA-approved device is the UroLift System.

Transrectal thermotherapy purportedly heats the prostate using a catheter inserted into the rectum. Various types of energy, such as microwave, radiofrequency or electrothermal, are delivered via the catheter to heat and thereby destroy excess prostate tissue.

Transurethral balloon dilatation involves the insertion of a balloon catheter through the urethra into the prostatic urethra where it is inflated, theoretically pushing back prostate tissue and stretching the urethra where it has been narrowed by the prostate. An example of this includes, but may not be limited to the Optilume Basic. **The Optilume drug-coated balloon** combines urethral dilation with circumferential topical delivery of paclitaxel.

Transurethral ultrasound guided laser induced prostatectomy (TULIP) is similar to TUIP except that cuts are made with a laser. Laser energy is delivered under ultrasound guidance, producing tissue necrosis.

Water induced thermotherapy (WIT) purportedly combines compression and high temperature to kill and shrink prostatic tissue surrounding the urethra. A heat-transmitting balloon catheter full of heated water (60 degrees Celsius) is introduced into the urethra, destroying prostate tissue.

Waterjet ablation (AquaBeam) is an endoscopic device intended to resect the prostate. The system is guided robotically using transrectal ultrasound imaging enabling the removal of the enlarged prostate tissue using a pressurized fluid jet.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Benign prostatic hyperplasia (BPH) treatment using the following methods will be considered medically reasonable and necessary when <u>nonsurgical management</u> has failed and the following requirements are met:

- Laparoscopic or open prostatectomy; OR
- Laser therapies, including the following:
 - Contact laser ablation of the prostate (CLAP); OR
 - Holmium laser ablation/enucleation/resection (HoLAP, HoLEP, HoLRP); OR
 - Interstitial laser coagulation (ILC); OR
 - Noncontact visual ablation (VLAP); OR
 - Photoselective vaporization of the prostate (PVP); OR

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- Thulium laser enucleation of the prostate (ThuLEP); OR
- Prostatic urethral lift (PUL) (UroLift) in an individual 45 years of age or older with prostate volume between 30-100cc and verified absence of an obstructive middle lobe¹; OR
- Transurethral electrical vaporization of the prostate (TUEVP, TUVP, TVP) or transurethral vapor resection (TUVRP); **OR**
- Transurethral incision of the prostate (TUIP) in an individual with a prostate volume less than or equal to 30cc¹; **OR**
- Transurethral microwave thermotherapy (TUMT); **OR**
- Water Vapor Thermal Therapy (WVTT) (Rezum System) in an individual 50 years of age or older with a prostate volume between 30-80cc¹; OR
- Transurethral resection of the prostate (TURP); OR
- Waterjet ablation (AquaBeam) in an individual with a prostate volume between 30-150 cc

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

The following **BPH treatments** will not be considered medically reasonable and necessary:

- Absolute ethanol injection; OR
- Cryosurgical ablation; OR
- High-intensity focused ultrasound (HIFU); OR
- Permanent urethral stent; OR
- Plasma kinetic vaporization (PKVP); OR
- Prostate artery embolization (PAE); OR
- Temporary prostatic urethral stent (iTind); OR
- Transperineal laser ablation (TPLA); OR
- Transrectal thermotherapy; OR
- Transurethral balloon dilatation (eg, Optilume Basic or drug-coated balloon); OR
- Transurethral needle ablation (TUNA)/radiofrequency needle ablation (RFNA); OR
- Transurethral ultrasound guided laser induced prostatectomy (TULIP); OR

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Water induced thermotherapy (WIT)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

Summary of Evidence

Plasma Kinetic Vaporization (PKVP)

Evidence from 10 randomized comparative trials indicates that PKVP can provide relief from BPH symptoms and improvement in urinary flow rate that is similar in magnitude to that provided by contemporary TURP, up to 1 year after surgery. Whether this treatment effect is maintained over a longer time remains unclear. PKVP may provide some advantages over TURP in terms of a reduced need for blood transfusion, decrease in catheterization time, and avoidance of TUR syndrome, although PKVP may be associated with a higher incidence of urethral complications than TURP. The quality of the evidence was moderate. Treating surgeons could not be blinded, and most studies failed to report adequate methods of randomization and allocation concealment. Bias in outcome assessment was likely due to infrequent reporting of blinding and the lack of criteria for postoperative catheter removal or for hospital discharge. The strength of the evidence was also limited by small study sizes and lack of long-term studies. Sources of financial support were not reported in any of the trials. Overall, the available evidence on the efficacy and safety of PKVP suggests that, in the short term, this minimally invasive treatment provides clinical outcomes that are similar to standard TURP for patients with BPH who cannot be adequately managed with medical therapy and who wish to reduce the risk of certain complications associated more frequently with TURP. Multicenter randomized studies with long-term follow-up and blinded assessment are needed to better define the role of PKVP in the treatment of BPH.³³

Prostate Artery Embolization (PAE)

Prostate artery embolization (PAE) is not supported by current data, and benefit over risk remains unclear; therefore, PAE is not recommended outside the context of clinical trials.¹

A moderately large body of evidence has found that PAE is reasonably safe but long-term efficacy has not been adequately evaluated. A low-quality body of evidence found that PAE when compared with TURP may:

- Be associated with less surgical trauma, less blood loss, fewer complications, and shorter HLOS.
- May be less effective. At 3 months to 2 years follow-up, TURP was more likely to provide statistically significant improvements in 1 or more prostate outcomes such as the International Prostate Symptoms Score, postvoid residual volume, peak urinary flow, and prostate volume. Although some of the studies of PAE versus TURP found no significant differences in some of these measures, none of the studies found a statistically significant advantage for PAE versus TURP in prostate outcomes.
- May also be somewhat safer.³⁰

A very low quality body of evidence comparing PAE with open prostatectomy does not provide sufficient evidence to assess comparative effectiveness and safety. Additional studies are needed to determine the

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long-term safety and effectiveness of PAE relative to TURP, other minimally invasive surgical treatments, and open prostatectomy for BPH as well as to establish patient selection criteria for PAE.³⁰

Evidence presented in a systematic review, a technology assessment, and two randomized controlled trials (RCTs) not included in the systematic review or technology assessment suggests PAE is not as effective as TURP but causes fewer adverse events. Both the SR and technology assessment reported that heterogeneity across studies limited their ability to make firm conclusions on PAE's effectiveness for treating BPH. Heterogeneity was due to differences in patient population, comparator, outcomes of interest, and methods. Most studies reported outcomes to only one year. Additional high-quality RCTs with longer follow-up and reporting on BPH recurrence are needed.¹⁶

Temporary Prostatic Urethral Stent (iTind)

iTind may improve LUTS, but network meta-analyses suggest improvements may be inferior to other minimally invasive and surgical options. Reviews each included 1 to 3 relevant studies of poor or fair quality, none of which directly compared iTind with other active treatments.²⁸

Evidence from three systematic reviews (SRs) suggests iTind reduces lower urinary tract symptoms secondary to BPH; however, how well iTind works compared with other BPH treatments cannot be determined from available comparative evidence because of insufficient quantity and quality. Large multicenter RCTs that report on patient-oriented outcomes at a longer follow-up (five years or more) are needed. Three ongoing trials may partially address evidence gaps.¹⁴

Transperineal Laser Ablation (TPLA)

Six before-and-after studies suggest TPLA reduces BPH related symptoms through one-year follow-up, these studies assess too few patients and are at too high a risk of bias to permit firm conclusions. No studies compare TPLA with TURP or with minimally invasive BPH treatments. Large, multicenter, randomized controlled trials (RCTs) are needed to validate the before-and-after studies' findings and to compare TPLA with other treatments. 18

Transurethral Needle Ablation (TUNA)/Radiofrequency Needle Ablation (RFNA)

No new studies on effectiveness and safety have been published. Based on the lack of peer-reviewed publication in the literature and TUNA's substantially diminished clinical relevance, the American Urological Association Panel does not recommend TUNA.¹

Water induced thermotherapy (WIT)

There is insufficient evidence to conclude that water-induced thermotherapy (WIT) is safe and effective for the treatment of benign prostatic hyperplasia (BPH). While the limited available published data suggest that WIT can provide therapeutic results comparable with those reported for other minimally invasive types of BPH treatment, there has been no direct comparison of WIT with other treatment options for BPH. In addition, optimal WIT protocols have not been established, and information regarding the duration of treatment effect or any long-term adverse effects is lacking.³⁷

Coding Information

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Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	
52282	Cystourethroscopy, with insertion of permanent urethral stent	
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant	
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)	
52450	Transurethral incision of prostate	
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	
52630	Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	
52647	Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)	
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	
52649	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)	

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53850	Transurethral destruction of prostate tissue; by microwave thermotherapy	
53852	Transurethral destruction of prostate tissue; by radiofrequency thermotherapy	
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement	
55801	Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy)	
55821	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages	
55831	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal	
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	
55899	Unlisted procedure, male genital system	
CPT®		
Category III Code(s)	Description	Comments
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)	
0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	
0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance	
HCPCS Code(s)	Description	Comments
C2596	Probe, image guided, robotic, waterjet ablation	
C2596 C9739	Probe, image guided, robotic, waterjet ablation Cystourethroscopy, with insertion of transprostatic implant; one to three implants	

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1 (4/64	Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts	
KIUUh	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system	
L8699	Prosthetic implant, not otherwise specified	

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Change Summary

01/01/2024 New Policy.